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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/689,515 | 06/01/2004 | Ravi Shrivastava | S112.12-0002 | 8626 |

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| EXAMINER | |
|---|---|
| ARNOLD, ERNST V | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/689,515 | SHRIVASTAVA ET AL. | |
| | Examiner | Art Unit | |
| | Ernst V. Arnold | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/20/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The Examiner acknowledges receipt of application 10/689,515 filed on 06/01/2004. Claims 1-15 are pending and are accordingly presented for examination on the merits.

### *Information Disclosure Statement*

The information disclosure statement filed 10/20/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered and the Examiner has drawn a line through the reference.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Howard (US 4,237,118).

Claim 1 is drawn to: A composition containing at least two vitamins of vitamin A, vitamin B2, vitamin B9 or vitamin E along with at least two minerals or trace-elements of

magnesium, zinc, copper and selenium in an amount effective for reduction of intracellular lipids and toxic wastes which have accumulated in a human body.

Howard discloses a composition in the form of a nutritional product comprising vitamin A, folic acid, vitamin E and magnesium and zinc for the treatment of obesity thus reading on instant claims 1 and 13 (Abstract; column 11, lines 19-46 and claims 1-16, for example). An emulsifier, polyoxethylene sorbitan mono oleate is an excipient in the composition thus reading on instant claims 2 and 14. Choline, a regulator of fat metabolism where deficiency in choline leads to fat accumulation in the liver (thus weight gain), is in the composition and reads on instant claims 3 and 15.

Howard discloses methods for treating obesity with the composition in which an individual ingests a daily diet having a total calorie content of not greater than 600 Kcals ( a hypocaloric diet) and consisting essentially of skim milk and the supplement which reads on oral administration of the composition of instant claims 4-9 (Claims 17-26). Howard discloses that the supplement described in Example 1 can be distributed as three 40 g meals mixed with 0.5 liters of water before use thus reading on instant claims

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (in an amount effective for reduction of intracellular lipids and toxic wastes which have accumulated in a human body), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In

the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

***Claim Rejections - 35 USC § 102***

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Howard (US 4,009,265).

Howard discloses methods and formulations for the treatment of obesity (Abstract). The formulations comprise vitamin A, riboflavin, folic acid, magnesium, zinc and an emulsifier polyoxyethylene sorbitan monooleate thus reading on instant claims 1-3 (Column 10, Table 1). The dietary formulation is normally administered in water (Column 9, lines 63-64). Howard discloses methods of treating obesity in man where the total caloric value of the daily diet is in the range of 160 to 600 Kcals thus reading on instant claims 4-9 (Claims 1-20).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (in an amount effective for reduction of intracellular lipids and toxic wastes which have accumulated in a human body), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

***Claim Rejections - 35 USC § 102***

Claims 1-3 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Andon et al. (US 5,571,441).

Andon et al. disclose a nutritional supplement composition comprising vitamin A, riboflavin, zinc, copper, magnesium stearate (a pharmaceutically acceptable excipient) and caffeine thus reading on instant claims 1-3 and 13-15 (Column 10, lines 16-column 11, line 15 and claims 1-22, for example).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (in an amount effective for reduction of intracellular lipids and toxic wastes which have accumulated in a human body), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

***Claim Rejections - 35 USC § 102***

Claims 1, 2, 4, 5, 7, 8, 10, 11 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Saiki et al. (GB 2038157).

Saiki et al. disclose a food composition for the manufacture of foods capable of reducing caloric intake to minimum requirements comprising vitamin and mineral components (Abstract). The vitamin and mineral components include vitamin A, vitamin B2, vitamin E, folic acid, zinc, and magnesium and admixed with a non-nutritional carrier (an excipient) thus reading on instant claims 1 and 2 (Claims 1 and 31). An example is provided of the food being fed to subjects and the subjects then performed daily exercise simulating bicycle riding thus reading on the methods of claims 4, 5 and 10, 11 and 13-15 (Page 4, lines 23-34). The diet of the test group was 10% lower than the control group thus the test group had a hypocaloric diet and reads upon instant claims 7 and 8 (Page 4, lines 11-22).

With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (in an amount effective for reduction of intracellular lipids and toxic wastes which have accumulated in a human body), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In

the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (US 4,237,118) in view of Votruba et al. (Nutrition 2000, 16, 179-188).

The reference of Howard is described in detail above and that discussion in hereby incorporated by reference.

Howard does not expressly disclose a method for reducing intracellular lipids and toxic wastes that have accumulated in the human body further comprising physical exercise or muscular electrostimulation with oral administration.

Votruba et al. provide a general teaching that exercise is strongly associated with improved weight maintenance (Page 187, left column, first paragraph).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include exercise, as suggested by Votruba et al. with the method of treating obesity of Howard for the purpose of losing weight and keeping it off and produce the instant invention. In addition, the use of laxatives, certain popular diets

(e.g., Atkin's or South beach) and other forms of exercise are known to one of ordinary skill in the art for weight reduction.

One of ordinary skill in the art would have been motivated to do this because it is desirable to keep the weight off and not regain the weight lost by diet.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA

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